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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,450	11/27/2006	Kristofer Olofsson	1090-127	8515
23117 7590 11/10/2008 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203				
EXAMINER				
RICCI, CRAIG D				
ART UNIT		PAPER NUMBER		
1614				
MAIL DATE		DELIVERY MODE		
11/10/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/590,450

**Applicant(s)**

OLOFSSON ET AL.

**Examiner**

CRAIG RICCI

**Art Unit**

4161

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-32 and 34-36 drawn to a compound of formula (I) and compositions.

Group II, claim(s) 1-33, drawn to a method of using the invention of Group I.

Group III, claim(s) 1-32 and 37, drawn to a method of making the invention of Group I.

Claims 1-25 and 30-32 are use claims. Use claims are non-statutory subject matter because they embrace or overlap more than one statutory class of invention. Accordingly, they have been placed into the Groups of Inventions set forth above. In response to this Office Action, Applicant is required to either amend the use to conform with US practice or cancel the claims.

2. As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), "the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept." Moreover, as stated in PCT Rule 13.2, "where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or

more of the same or corresponding special technical features." Furthermore, Rule 13.2 defines "special technical features" as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

3. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is a compound of formula (I). The compounds of claim 26 do not present a contribution over the prior art. As disclosed by *Mistryukov et al* (Izvestiya Akademii Nauk SSSR, 292-294, 1961) - as evidenced by the attached STN search - the special technical feature of instant claim 26 is not novel. Specifically, RN 856640-00-1 anticipates claim 26:

L4 ANSWER 24 OF 26 CAPLUS COPYRIGHT 2008 ACS on BIN  
 ACCESSION NUMBER: 1961:99450 CAPLUS Full-text  
 DOCUMENT NUMBER: 55:99450  
 ORIGINAL REFERENCE NO.: 55:16726a-c  
 TITLE: Synthesis of four geometric isomers of  
 1,2,3-trimethyl-4-phenyl-4-piperidinol  
 Mistryukov, E. A.; Shvetsov, N. I.  
 AUTHOR(S): N. D. Zelinskii Inst. Org. Chem., Moscow  
 CORPORATE SOURCE: Izvestiya Akademii Nauk SSSR, Seriya Khimicheskaya  
 SOURCE: (1961) 292-4  
 CODEN: IASZAA; ISSN: 0002-3353  
 DOCUMENT TYPE: Journal  
 LANGUAGE: Unavailable

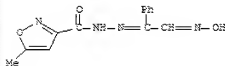
AB cf. CA 53, 21946b. 1,2,3-Trimethyl-4-piperidinone and PhLi gave mainly  
 the  $\alpha$ -isomer of 1,2,3-trimethyl-4-phenyl-4-piperidinol, m.  
 143-5° (least soluble in MePh); a lesser amount of the  $\beta$ -isomer, m.  
 118-19°, was isolated from the mother liquors.  $\alpha$ -Isomer HCl  
 salt m. 180-3°;  $\beta$ -isomer HCl salt m. 190-5°. The  
 reaction gave a low yield of the  $\gamma$ -isomer, m. 96-7°; HCl salt  
 m. 246°. Treatment of the  $\alpha$ -isomer with dry HCl, followed by  
 SOCl<sub>2</sub> in CHCl<sub>3</sub> (3 h. at reflux) and treatment of the product with aqueous  
 NaOH gave a dehydration product, b.p. 110-15°, which was treated with  
 HBr in AcOH overnight and then treated with aqueous NaOH to yield 25%  
 $\gamma$ -isomer of 1,2,3-trimethyl-4-phenyl-4-piperidinol, b.p.  
 132-40°, m. 109-11°.

IT 100725-02-5F, Hydrazine, 1- $\alpha$ -formylbenzylidene-2-(5-methyl-3-  
 isoxazolylcarbonyl)-, oxime 856680-00-1F, Hydrocinnamic acid,  
 $\alpha,\beta$ -dicyno-, ethyl ester,  $\alpha$ -oxime, (5-methyl-3-  
 isoxazolylcarbonyl)hydrazone  
 RI: PREP (Preparation)

(preparation of)

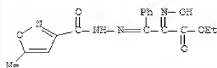
RI 100725-02-5 CAPLUS

EN 3-Isioxazolecarboxylic acid, 5-methyl-, 2-[2-(hydroxyimino)-1-  
 phenylethnylidene]hydrazide (CA INDEX NAME)



RI 856640-00-1 CAPLUS

EN 3-Isioxazolecarboxylic acid, 5-methyl-, 2-[3-ethoxy-2-(hydroxyimino)-3-oxo-  
 1-phenylpropylidene]hydrazide (CA INDEX NAME)



. As such, Group I does not share a special technical feature with the instant claims of Group II-III. Therefore, the claims are not so linked within the meaning of PCT Rule 13.2 so as to form a single inventive concept, and unity between Groups I-III is broken.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP

§ 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

#### ***Election of Species***

6. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If any of Groups I-III is elected, the following species election is required:

a) A single compound species of formula (I);

If Group I is elected, the following species is also required:

b) A pharmaceutical formulation (single or combination formulation);

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, Applicant is required to define each of  $R^1$ - $R^{15}$ ,  $A^1$ - $A^{24}$ ,  $X^1$ - $X^3$ , Z, n, Q, W and any additional variables as required to define the elected compound species. In defining each variable as to the elected compound species, Applicant is reminded that a species for example is methyl, NOT alkyl. Additionally, if Group I is elected, Applicant is also required to elect whether the formulation includes the elected compound **OR** the elected

compound in combination with another therapeutic agent. Upon Applicant's election of species, the result must provide a single chemical species and formulation. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. The claims are deemed to correspond to the species listed above in the following manner: claims 2-32 and 34-36 as to Group I; claims 2-33 as to Group II; and claims 2-32 and 37 as to Group III. The following claim(s) are generic: claim 1 as to Group I; claim 1 as to Group II; and claim 1 as to Group III.

8. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

a) each chemical species is a distinct chemical which lacks a special technical feature in view of *Mistryukov et al* (Izvestiya Akademii Nauk SSSR, 292-294, 1961) as evidenced by the attached STN report.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of



search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the

prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/CRAIG RICCI/  
Examiner, Art Unit 4161

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614